

**REMARKS**

Claims 51-66 are all the claims pending in this application.

Initially, Applicants respectfully request a personal interview with the Examiner at the Examiner's convenience, and submit herewith a Request for a Personal Interview.

On pages 2-4 of the Office Action, claims 51-57 and 59-67 are rejected under 35 U.S.C. 103(a) as unpatentable over Suzuki. In addition, claim 58 is presumably rejected under 35 U.S.C. § 103(a) as being unpatentable over Suzuki in view of Makino.

Basically, the Examiner's position is substantially the same as that set forth in the previous Office Actions.

Applicants respectfully respond as follows.

The present invention is directed to a composition where more drug is dispersed on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material. Applicants respectfully submit that the composition of the present invention is different from that of Suzuki and would not be expected based on the disclosure of Suzuki alone or in view of Makino. In addition, Applicants respectfully submit that the present invention provides unexpected results, as shown by the evidence of record.

In the Office Action, the Examiner indicates that Comparative Example 67 does not seem to correspond to any of the Examples of Suzuki.

The method used in Comparative Example 67 is freeze drying a solution of a drug and a water-absorbing and gel-forming base material (*see* the sentence bridging pages 35-36 in the present specification). The method of Example 1(b) of Suzuki is freeze drying a drug and a water-absorbing and water-soluble base material (*see* col. 7, lines 34-38). Therefore, the method of Comparative Example 67 corresponds to the method used in Example 1(b) of Suzuki.

In addition, Suzuki's water-absorbing and water-soluble base material corresponds to the present invention's water-absorbing and gel-forming base material. For example, hydroxypropyl cellulose is a water-absorbing and water-soluble base material in Suzuki (*see col. 5, line 15*) and a water-absorbing and gel-forming base material in the present invention (*see, e.g., page 4, lines 36-38 in the present specification*).

Further, Comparative Example 67 is even closer to the present invention than Example 1(b), because Comparative Example 67 uses hydroxypropyl cellulose as its water-absorbing and gel-forming base material (hydroxypropyl cellulose is a water-absorbing and gel-forming base material of the present invention) while Example 1(b) uses polyacrylic acid (sodium polyacrylate) as its water-absorbing and water-soluble base material (polyacrylic acid/sodium polyacrylate is not a water-absorbing and gel-forming base material of the present invention). MPEP §716.02(e) states that Applicants may compare the claimed invention with that which is more closely related to the invention than the prior art relied upon by the examiner. Therefore, it is appropriate to compare an invention with a comparison embodiment that is closer to the invention than is the closest prior art example. Accordingly, it is respectfully submitted that comparing the present invention with Comparative Example 67 is appropriate for showing unexpected results.

Next, the Examiner indicates that it is not possible to compare Example 1(b) of Suzuki with the composition of the instant invention since Example 1(b) of Suzuki does not contain a cellulose as the water-absorbing and gel-forming base material, even though Suzuki teaches celluloses as base materials in the body of his reference

It is respectfully submitted that Example 1(b) of Suzuki can be compared to the present invention, even though it does not contain a cellulose as the water-absorbing and gel-forming base material. MPEP §716.02(e) states that the claimed invention can be compared with the

closest specific example in the prior art, and thus it is appropriate to compare Example 1(b) of Suzuki with the present invention.

Also, even if Example 1(b) of Suzuki could not be compared to the present invention, Comparative Example 67 can be compared to the present invention and is even closer to the present invention than is Example 1(b) as discussed above. Therefore, the comparison of Comparative Example 67 with the present invention is probative of the patentability of the present invention.

The Examiner also states that it is not clear that Comparative Example 68 is a method taught by Suzuki.

Based on the October 22, 2001 Declaration, the method used in Comparative Example 68 is a mechanical mixing method using a ball-free mill to mix a drug, a water-absorbing and water-insoluble base material, and a water-absorbing and gel-forming base material in one step. Suzuki at col. 6, lines 10-14 and 39-43 discloses that a water-absorbing and water-soluble base material and a water-absorbing and water-insoluble base material can be mixed together simultaneously with a drug in a mechanical mixing process. Therefore, Comparative Example 68 corresponds to this method in Suzuki.

As to the Examiner's assertion that it is impossible to compare the examples of Suzuki with those of the instant invention because Suzuki does not exemplify a composition comprising both the preferred water-absorbing/gel-forming base and water-absorbing/water-insoluble base, even if this were true, Applicants have compared the present invention with a comparison example (Comparative Example 68). Comparative Example 68 is closer to the present invention than is any of the Suzuki examples because Comparative Example 68 uses both a water-absorbing and water-insoluble base material and a water-absorbing and gel-forming base material. As discussed above, since it is appropriate to compare an invention with a comparison

embodiment which is closer to the invention than is the closest prior art example, comparing the present invention with Comparative Example 68 is appropriate.

The Examiner further notes that as pointed out in the previous Office Action, Suzuki discloses at col. 5, lines 53-65 that the drug may be adhered to or dispersed in the water-insoluble base, and that Suzuki does not teach that the drug is adhered to or dispersed in the gel-forming base. Therefore, the Examiner concludes that even with the addition of a gel-forming base, it is reasonable to expect that the drug would be more adhered to or dispersed in the water-insoluble base.

Applicants have presented evidence showing that the drug would not be more adhered to or dispersed in the water-insoluble base in Suzuki. For example, Applicants direct the Examiner's attention to page 8 in the March 14, 2001 Declaration. The Declaration shows that although some drug is adhered to or dispersed in the water-absorbing and water-insoluble base material in Suzuki, the drug is not dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material. Also, the Examiner's attention is directed to the October 22, 2001 Declaration, which shows that in three different methods disclosed in Suzuki, the drug is not dispersed more on or in the water-absorbing and water-insoluble base material than on or in the water-absorbing and gel-forming base material. Therefore, contrary to the Examiner's assertion, the drug does not adhere to or disperse more in the water-insoluble base in Suzuki, and the effects of the present invention would not be expected based on Suzuki.

The Examiner also asserts that instant claims are product-by-process claims, and thus determination of patentability is based on the product itself.

With respect to the product-by-process claims, if the process by which the product is made affects the product, such that the product is different from the prior art, then the process

limitations define the invention. In this case, the compositions made by the processes of the present invention are different than the products made by the processes of Suzuki. This can be seen from the evidence of record in the present case. As mentioned above, Applicants have compared compositions of the present invention prepared by the processes of the present invention to a composition obtained by processes disclosed by Suzuki. For example, the compositions of the present invention (Examples 75, 76 and 77) compared to comparative Example 68 had a larger AUC and higher Cmax. Accordingly, the processes of the present invention result in a composition that is different from the composition of Suzuki.

Regarding the argument that "Applicants have provided facts that the drug adheres more to the water-absorbing and water-soluble base when the drug is freeze-dried with the water-absorbing and water-soluble base material", the Examiner asserts that this argument is not commensurate in scope with the instant independent claims, which do not recite a method of freeze-drying.

In this regard, Applicants respectfully point out that, for example, independent claim 52 recites freeze drying at lines 21-22 of the claim.

Finally, the Examiner indicates that she is unable to find any photographs submitted with the Declaration of February 22, 2000 (actually, February 24, 2000).

Applicants respectfully submit that the Declaration was originally filed in the PTO mailroom and that a copy was subsequently faxed to the Examiner. However, since the Examiner is unable to locate the photographs, they are submitted herewith.

In view of the above, it is respectfully submitted that the composition of the present invention is different from and unobvious over the composition of Suzuki alone or in view of Makino. Accordingly, Suzuki does not teach or suggest the present invention, and withdrawal of the foregoing rejections is respectfully requested.

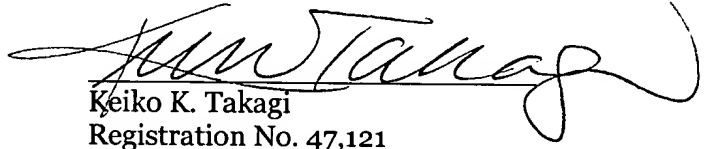
**AMENDMENT UNDER 37 C.F.R. § 1.116**  
**U.S. Application No.: 09/125,814**

**Attorney Docket No.: Q51505**

Reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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WASHINGTON OFFICE

**23373**  
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